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Zydus receives approval from DCGI for diabetes drug

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Zydus' Saroglitazar Magnesium has been approved for the treatment of diabetes mellitus type 2 by the Drug Controller General of India

Zydus Cadila, an innovation-driven, global pharmaceutical company, announced that it has received the approval from the Drug Controller General of India (DCGI) for use of Saroglitazar Mg in the treatment of Type II Diabetes Mellitus as an add on therapy with Metformin.

The drug was previously approved in the year 2013 for the treatment of Hypertriglyceridemia and Diabetic Dyslipidemia in India. More than 1 Million patients are being treated with Lipaglyn.

The Diabetes Phase 3 clinical trial was a Multi-centric, Prospective, Randomized, Double- blind Study to Evaluate the Safety and Efficacy of Saroglitazar Mg 2 mg and 4 mg as compared to Pioglitazone 30 mg in patients with type 2 diabetes.

The Phase 3 trial conducted in 1140 type 2 diabetes patients for a total of 56 weeks met the primary end-points (CTRI/2015/09/006203). The primary outcome measure was the change from baseline in glycosylated hemoglobin (HbA1c) for Saroglitazar 4 mg, 2 mg and Pioglitazone 30 mg at 24 weeks.

The secondary outcome measures included the change from baseline in fasting plasma glucose, 2 hour postprandial plasma glucose, lipid profile, Triglyceride (TG) cholesterol, Low density lipoprotein (LDL) cholesterol, Very low density lipoprotein (VLDL) cholesterol, High density lipoprotein (LDL) cholesterol, Total cholesterol (TC) cholesterol, Non HDL cholesterol, Apolipoprotein (Apo) A1 and Apo B between Saroglitazar (4 mg, 2 mg) and Pioglitazone (30 mg) treatment at Week 12, 24 and 56.

In Phase III diabetes trial, at 24 weeks, HbA1c was reduced by 1.38 g/dL with Saroglitazar 2 mg, 1.47 g/dL with Saroglitazar 4 mg and 1.41 g/dL with Pioglitazone 30 mg. At 56 weeks, HbA1c reduced by 1.34 g/dL with Saroglitazar 2 mg, 1.49 g/dL with Saroglitazar 4 mg and 1.47 g/dL with Pioglitazone 30 mg. Saroglitazar did not cause hypoglycemia or weight gain in this trial.

Lipalgyn™ was first launched in India during September 2013. Over the last several years, more than 1 Million patients have been treated with Lipaglyn™ in India for management of Hypertriglyceridemia and Diabetic Dyslipidemia, and data has been presented at several scientific and medical conferences